Half year report

H1 Following the road paved by FDA breakthrough designation

SIGNIFICANT EVENTS (During and after the period)

- The company has initiated interactive discussions under the Breakthrough Device Designation program regarding the registration of RemeOs ™ trauma screws for the US market.
- The orthopedic market continues to show signs of recovery during the period, after the pandemic market turbulence and net sales grew 44% compared to the corresponding period of 2020.
- Relocation to new facilities is proceeding as planned and will be completed during Q3 2021.
- The company planned to finalize an IPO and listing on Nasdaq First North Growth Market Finland marketplace in June 2021. The Board of Directors of Bioretec decided to cancel the Offering based on the conclusion of the sole global coordinator and bookrunner of the offering, that the offering could not be completed. The offering, including the over-allotment option, was oversubscribed, but not to a sufficient degree such that the development of the Bioretec share on the secondary market could be expected to be beneficial to Bioretec and the investors.
- On June 22, the company organized funding round in collaboration with Springvest Oy. The share issue was fully subscribed, and the total amount of new equity raised was 7.2 M€.
- No significant events have occurred after the period.

KEY FINANCIALS H1 / January – June 2021

- Net sales increased by 44% compared to the same period in 2020 and amounted to 1.0 M€ (H1/2020: 729 k€).
- The Europe area reported net sales of 526 k€ (346 k€). The increase in sales was due to the market opening after the pandemic, mainly in Austria, Bulgaria, Denmark, Spain, and Slovakia.
- The ROW (Rest of the World) area reported net sales of 472 k€ (351 k€). A notable increase took place in China having high demand after the pandemic.
- The net sales in the USA remained at last year's level.
- The Sales Margin was 74% and in line with the comparison period (75 %).
- Net profit (loss) amounted to -2.8 M€ (-1.37 M€). The costs related to cancelled IPO and listing as well as completed funding round were included in the H1 2021 income statement and were approximately EUR -1.6 million.
- The company continued to invest in the development of the new RemeOs™ product line.
- The Annual General meeting on April 22, 2021, decided on a reverse split of company shares, where the number of shares was divided by 15. The impact of the reverse split has been registered in the trade register on April 23, 2021. As a result, the number of shares has decreased during the period.

Key Figures (1000 Euros, non-audited)	H1 2021	H1 2020	FY 2020
Net Sales	**1 047**	729	**1 499**
Sales Margin	**778**	549	**1 103**
Sales Margin%	**74,3 %**	75,3 %	**73,5 %**
EBITDA	**-1 157**	-970	**-1 787**
EBIT	**-1 227**	-1 038	**-1 925**
Net profit (loss)	**-2 791**	-1 367	**-2 259**
R&D spend on total costs (%)	**39 %**	21 %	**24 %**
Equity ratio (%)	**57 %**	39 %	**35 %**
Cash and cash equivalents	**865**	2 652	**2 273**
Earnings per share (undiluted)	**-259,7**	-9,1	**-15,0**
Earnings per share (diluted)	**-146,1**	-5,9	**-10,3**
Number of shares at the end of the period	**10 747 858**	150 007 527	**150 402 068**
Number of shares (diluted)	**19 099 006**	229 998 830	**218 724 369**
Personnel[1]	**24**	24	**23**

[1] Number of personnel at the end of the period

CEO'S COMMENTS ON THE FIRST HALF OF 2021

The target is to commercialize RemeOs™ trauma screws

The company's first half year was eventful with several successes. The company issued a successful share issue and raised EUR 7.2 million in new capital to stabilize its financial position and to meet its operational targets to achieve market authorizations for RemeOs™ trauma screws in the US and European markets in 2022. In May, the company began interactive discussions with the FDA under the Breakthrough Device Designation program regarding the registration of RemeOs™ trauma screws for the US market. During the first half of the year, the company has been preparing for the relocation to a new, more suitable facility, and the relocation project has progressed as planned with the target of being fully operational during the third quarter at the new premises.

RemeOs ™ trauma screws were approved by the US Food and Drug Administration's (FDA) under the Breakthrough Device Designation program during the spring. Discussions with the FDA on the content of, and studies required for, the marketing authorization application are ongoing on a weekly basis. We are excited about this opportunity to interactively discuss our study protocols and results with the experts of the FDA. In case of any findings requiring further studies, this interactive discussion will enable the company to react as quickly as possible and correct the situation already before the submission of the market approval application. The company aims to complete its De Novo registration in the first half of next year and then launch its RemeOs™ trauma screw products in the US market.

In Europe, the new Medical Device Regulation (MDR) came into force in May, and therefore we have updated our operations and procedures to comply with the new Medical Device Regulation (MDR) during the past months. New RemeOs™ products will be registered under the new regulations following the notified body audits in July and September.

The first half of the year also showed signs of a recovery in healthcare systems and markets globally, and the company's revenue grew 44% from the 2020 comparison period. However, it is still difficult to assess market behavior towards the end of the year based on the current information available, especially as new COVID-19 variants appear to be emerging at a steady pace.

The eventful spring has also included a relocation project to new premises in Tampere that are better suited for the company. The new facilities will enable better production and cleanroom facilities for the manufacture and sterilization of the new RemeOs™ products, as well as more comprehensive research and development facilities for the development of new products. The RemeOs™ Dry hot-air sterilization method for trauma screws in our own production facilities also creates a significant advantage and economic savings compared to our current products, which are radiation sterilized by a subcontractor outside Finland.

After an eventful half year, I am confident we will continue our systematic and steady progress with the same enthusiasm and determination.

Timo Lehtonen, CEO

SALES AND MARKETING

The sales trend continued in line with the first quarter

The first quarter already showed signs of recovery in the healthcare market, and the second quarter continued with the same trend despite the continuation of the COVID-19 pandemic and new virus variants. Sales for the period increased by 44% compared to the comparison period of 2020, and net sales for the period are now one of the highest ever in Bioretec's history. Sales in Asia have been excellent throughout the first half of the year and continue to follow the trend that began last year. European demand has also recovered during the second quarter.

Similarly, like almost all industries around the world, the orthopedics industry is recovering from the impact of the coronavirus pandemic on sales in 2020, and the number of elective surgeries is growing and will gradually return to possibly pre-pandemic norms in 2022 based on the industry forecasts. In terms of sales and marketing, the second quarter brought very promising results from the continued recovery in sales that began during the first quarter. For the rest of the year, it is still difficult to assess the continuation of the trend, as new variations of the COVID-19 virus may cause new national constraints globally. Net sales for the period were one of Bioretec's best, and sales increased by 44% compared to the same period last year. According to the company's unaudited result, sales in the first half of 2021 ended in the review period at 1047 k€. The company's sales in Asia have been growing for several quarters. In Europe, the company's sales were clearly better (+52%) than in the comparison period.

Net sales in the European region were EUR 526 thousand (compared to EUR 346 thousand in the previous year). The increase in sales was due to the opening of the market after the pandemic in Austria, Bulgaria, Denmark, Spain, and Slovakia, among others. Correspondingly, net sales from the rest of the world were EUR 472 thousand (EUR 351 thousand). The growth was mainly driven by significantly increased demand in Asia following the calmed pandemic situation. Reported US revenue remained at last year's level due to the impact of COVID-19 on the health care system.

Over the past year, the company has changed its marketing strategy to adapt to the current situation, where gathering and travel restrictions have only supported virtual training events and webinars. The company will continue to use this proven strategy if conferences and training events are further restricted globally.

SALES BY GEOGRAPHICAL AREA

(1000 Euros)	H1 2021	H1 2020	FY 2020
Europe[1]	**526**	346	**697**
US	**50**	33	**68**
ROW (rest of world)	**472**	351	**734**
TOTAL	**1 047**	**729**	**1 499**

[1] Russia included in Europe

RESEARCH AND DEVELOPMENT

R&D Focus on RemeOs™ screw registrations

The preparation of RemeOs ™ trauma screw's marketing authorization applications for the United States and Europe is progressing as planned. The program under the Breakthrough Device Designation status granted by the FDA was launched in May, and the interactive discussions, the so-called Sprint discussions, are ongoing regarding the registration of RemeOs™ trauma screws for the US market.

Bioretec's RemeOs™ screw met the demanding criteria of the US FDA Breakthrough Device for proposed indications. Bioretec's RemeOs™ screws are intended for use in traumatic surgery/traumatology and orthopedic surgery for the fixation of bone fractures (osteosynthesis) and osteotomies, and for the correction of deformities or malalignments. The implants serve as temporary fixation and stabilization by osteosynthesis of bones and fragments until bony fusion has occurred.

According to the FDA, a Breakthrough Device provides a more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. Additionally, a Breakthrough Device represents breakthrough technology or offers significant advantages over existing approved or cleared alternatives. The benefits include the potential to reduce or eliminate the need for hospitalization, improve patient quality of life, or establish long-term clinical efficiencies. Under the program, the FDA will provide Bioretec with priority review and interactive communication regarding device development and clinical trial protocols, through to commercialization decisions.

A new investigator-initiated clinical trial (IIS) was launched during the first half of the year to extend the use of the pediatric Activa IM-Nail™ to treat pediatric wrist fractures (Distal radius). The first operations with this novel treatment of children's wrist fractures have now been completed, and the study will continue as planned.

Post Market Clinical follow-up study of Activa IM-Nail™ in CE-marked indication continues as planned, but patient enrollment has been slower than anticipated due to COVID-19 restrictions. The investigation is ongoing in Hungary, Denmark, and Austria. Ethical committee approvals are continuing in Germany, France, UK, Sweden, Portugal, and Switzerland.

Continuing global measures against COVID-19 and the need to prioritize healthcare resources may impact ongoing and forthcoming clinical trials. At present, Bioretec has no information on any consequences of COVID-19 other than those presented above. Updates will be provided when applicable.

PERIODICAL OUTLOOK

Financial overview H1/2021

PROFIT AND LOSS

Net sales and sales margin
Revenue of Bioretec group totaled 1 047 k€, an increase of 317 k€ (44%) compared to H1 2020. Growth was mainly due to higher sales of Activa products in both the Asian and European markets. The absolute sales margin was 778 k€, an increase of 229 k€ (42 %) compared to H1 2020. The main reason for improved absolute sales margin was due to higher net sales as the sales margin % remained at the same level as in the comparison period.

Operating Expenses
Bioretec group's total operating costs (including salaries, depreciation, and other operating expenses) were 2.0 M€ and ended up with an increase of 418 k€ (and 26 %) compared to H1 2020 (1.59 M€). The increase was mainly due to the high level of resourcing done to new product development. The company measures its RD spend (against the total operating costs) with a separate key figure RD spend % (on above total operating costs). RD spend % for H1 2021 was 39 % (782 k€) against 21 % during H1 2020 (335 k€).

EBITDA and Net profit (loss)
Bioretec group EBITDA was -1.16 M€ (-0.97 M€), decreasing slightly compared to last year. Net loss of the period was -2.8 M€ (-1.4 M€) and significantly weaker due to realized costs of both planned IPO and additional Springvest financing round. The total impact of these financing rounds at H1 2021 PL is -1.6 M€. Financing costs at comparison period include Springvest 2020 financing round related costs -0.3 m€.

FINANCIAL POSITION AND CASH FLOWS

Investments totaled 139 k€ (62 k€) and were mainly related to Bioretec's relocation to new office and factory premises during Q3 2021. Operational cash flow totaled -1.2 M€ (-1.1 M€). The main reasons for the weakening of operational cash flow are due to increased RD spend and working capital.

PERSONNEL, MANAGEMENT AND THE BOARD OF DIRECTORS

The number of personnel at the end of the review period was 24 (24) persons. Bioretec's members of the Board of Directors were Tomi Numminen (Executive Chairman), Pekka Simula, Michael Piccirillo, and Hans Rosen. Changes occurred in the board composition during the period. On April 22, 2021, the annual general meeting elected Sarah Fisher as a new board member. At the end of June 2021, the Bioretec Board of Directors had five members.

SHARES AND RELATED PROGRAMMES

On June 30, 2021, Bioretec had 10 747 858 shares outstanding. From the shares outstanding, there were 532 625 shares not yet registered in the book-entry system. Company shares have been transferred to the Euroclear book-entry system on April 29, 2021. The above total number of shares excludes shares issued in Springvest offering in June as the shares were still unregistered on June 30, 2021.

The company had filed a listing application to Nasdaq First North Growth Market Finland at the beginning of June 2021. As the public offering did not occur as planned, the company canceled the listing application on June 17, 2021. The Board of Directors of Bioretec decided to cancel the offering based on the conclusion of Danske Bank A/S, Finland branch, acting as the sole global coordinator and bookrunner of the Offering, that the offering could not be completed. The cancellation of the offering is not based on reasons relating to Bioretec, its actions or financial position but to subscriptions received in the offering not being sufficient. The offering, including the over-allotment option, was oversubscribed, but not to a sufficient degree such that the development of the Bioretec share on the secondary market could be expected to be beneficial to Bioretec and the investors.

After the cancellation of the listing application, the company executed a share issue organized in collaboration with Springvest. The main reason for arranging the share issue was to ensure sufficient funding for the company. Shares were fully subscribed on June 22, 2021. During the share issue in total, 2.4 million new company shares were subscribed. The aim is to register subscriptions into the trade register and to subscriber´s book-entry accounts during August 2021.

The company held an Extraordinary General Meeting on July 9, 2021.

- Extraordinary General Meeting authorized the Board of Directors to resolve on an Option program 2021-1, based on which option rights shall be granted to Springvest Oy and its tied agents in relation to the terms of the agreement between the company and Springvest Oy concerning the organizing of a financing round for the company. Based on the authorization, the maximum number of shares that can be subscribed based on the option rights shall be 384,000 shares. Share subscription price of the shares to be subscribed based on the option rights shall be EUR 0,001 per share. The authorization shall be valid until December 31, 2021, and it does not cancel the previous authorizations granted to the Board of Directors.
- Extraordinary General Meeting authorized the Board of Directors to resolve on the issuance of shares as follows: Under the authorization, up to 1,333,333 shares can be issued. The shares can be issued in one or more tranches against a minimum subscription price of EUR 3.00 per share. The shares issued under the authorization can be new shares or shares in the company's

possession. The authorization can be used to strengthen the company's balance sheet and financial position or for other purposes determined by the Board of Directors. Under the authorization, the Board of Directors may resolve upon issuing new shares, without consideration, to the company itself. The Board of Directors is authorized to resolve on all other terms for share issues. The Board of Directors is authorized to resolve a directed share issue, provided that there is a weighty financial reason for the company to do so. The authorization is valid until the end of the next Annual General Meeting; however, no longer than until June 30, 2022. The authorization shall revoke previous unused share issue authorizations except for the authorization pursuant to section 6 and the authorization granted by the Annual General Meeting held on June 26, 2020, authorizing the Option Program 2020-1.

CONSOLIDATED INCOME STATEMENT [1]

(1000€ Euros)	H1 2021	H1 2020	FY 2020
REVENUE	**1 047**	729	**1 499**
Changes in stocks (FG and WIP)	**12**	97	**137**
Other operating income	**0**	0	**2**
Total materials and services	**-281**	-277	**-535**
Total personnel expenses	**-1 040**	-978	**-1 780**
Total depreciation and amortization	**-71**	-69	**-138**
Other operating expenses	**-894**	-540	**-1 109**
OPERATING PROFIT (LOSS)	**-1 227**	-1 038	**-1 925**
Net financial expenses	**-1 563**	-328	**-333**
Profit (loss) before taxes	**-2 790**	-1 366	**-2 258**
Income taxes	**0**	0	**-1**
PROFIT (LOSS) FOR THE PERIOD	**-2 791**	-1 367	**-2 259**

[1] non-audited

CONSOLIDATED BALANCE SHEET [1]

(1000 euros)	H1 2021	H1 2020	FY 2020
ASSETS			
NON-CURRENT ASSETS			
Intangible assets	**361**	458	**410**
Tangible assets	**357**	185	**240**
CURRENT ASSETS			
Total inventories	**724**	567	**672**
Short-term debtors	**7 878**	339	**298**
Cash and cash equivalents	**865**	2 652	**2 273**
TOTAL ASSETS	**10 184**	4 202	**3 892**
EQUITY AND LIABILITIES			
EQUITY			
Restricted share capital	**3 749**	9 221	**3 749**
Share issue	**7 204**	0	**610**
Other reserves (reserve for unrestricted equity)	**659**	17 008	**0**
Retained earnings (loss)	**-2 998**	-23 239	**-739**
Profit (loss) for the period	**-2 791**	-1 367	**-2 259**
LIABILITIES			
Long-term creditors	**1 940**	1 980	**1 977**
Short-term creditors	**2 421**	598	**555**
TOTAL EQUITY AND LIABILITIES	**10 184**	4 202	**3 892**

[1] non-audited

STATEMENT OF CHANGES IN EQUITY [1]

(1000 euros)	H1 2021	H1 2020	FY 2020
Share capital at the beginning of the period	**3 749**	9 221	**9 221**
Reduction of equity	**0**	0	**-5 473**
Restricted equity total at the end of the period	**3 749**	9 221	**3 749**
Share issues at the beginning of the period	**610**	0	**0**

Period changes	**6 595**	0	**610**
Share issues at the end of the period	**7 204**	0	**610**
Reserve for invested unrestricted equity at the beginning of the period	**0**	12 755	**12 755**
Reduction of equity	**0**	0	**-17 027**
Period changes	**659**	4 253	**4 272**
Reserve for invested unrestricted equity at the end of the period	**659**	17 008	**0**
Retained earnings at the beginning of the period	**-2 998**	-23 239	**-23 239**
Reduction of equity	**0**	0	**22 500**
Retained earnings at the end of the period	**-2 998**	-23 239	**-739**
Result of the period	**-2 791**	-1 367	**-2 259**
TOTAL EQUITY	**5 823**	1 624	**1 360**

[1] non-audited

FINANCIAL POSITION AND CASH FLOW [1]

(1000 euros)	H1 2021	H1 2020	H1 2021
CASH FLOW FROM OPERATING ACTIVITIES			
Cash flow before changes in working capital	**-1 157**	-970	**-1 157**
Change in Working Capital	**-83**	-98	**-83**
Net financial expenses and taxes paid	**-3**	-17	**-3**
CASH FLOW FROM OPERATING ACTIVITIES	**-1 243**	-1 085	**-1 243**
CASH FLOW FROM INVESTMENTS			
Investments for tangible and intangible assets	**-139**	-62	**-139**
CASH FLOW FROM INVESTMENTS	**-139**	-62	**-139**
CASH FLOW FROM FINANCING			
Paid share issues	**53**	4 004	**53**
Change in short- and long-term financing	**-37**	65	**-37**
Paid other financial expenses	**-43**	-327	**-43**
CASH FLOW FROM FINANCING	**-27**	3 742	**-27**
Change in liquid assets (+/-)	**-1 408**	2 594	**-1 408**
Cash and cash equivalents at the beginning of the period	**2 273**	58	**2 273**
Cash and cash equivalents at the end of the period	**865**	2 652	**865**

[1] non-audited

OTHER DISCLOSURES

BASIS OF PREPARATION OF THE HALF YEAR REPORT

The consolidated financial statements of the Bioretec group have been prepared in accordance with the Finnish Accounting Act, as well as the rules of Nasdaq First North Growth Market Finland. Bioretec Oy, Bioretec Technology Oy, and BRI Tech GmbH form the Bioretec group.

Accounting principles have not changed during the reporting period.

SIGNIFICANT RISKS AND UNCERTAINTIES

The company is exposed to various financial risks. The business is impacted by many factors that could affect the company's results and financial position. It is Bioretec's strategy to identify and manage risks continuously. The most important business-related risks are associated with the group's growth targets and their achievement with the company's chosen strategy and the sufficiency of funding to support the growth. Industry-related risks are mainly associated with target markets which are both highly regulated and conservative and where the introduction of new technologies happens slowly. Risks related to legislation, rules, and regulatory compliance are associated with the group's sector of industry. Risks associated with the group's financial position mainly comprise operative currency and credit risks.

The report contains certain forward-looking information that reflects Bioretec's current views of future events and financial and operational performance. Words such as "intends", "anticipates", "expects", "can", "plans", "estimates", and similar expressions regarding indications or forecasts of future developments or trends, and which are not based on historical facts, constitute forward-looking information. Forward-looking information is inherently associated with known and unknown risks and uncertainties because it depends on future events and circumstances. Forward-looking information is not a guarantee of future results or developments, and actual results may differ materially from results referred to in forward-looking information. Forward-looking information in the report is only applicable on the date of issue of the report. Bioretec does not commit to publishing updates or revisions of any forward-looking statements as a result of new information, future events or similar circumstances other than those required by applicable legislation.

DEFINITIONS OF KEY FIGURES

Key Figure	Calculation formula

Sales margin	Revenue + other operating income - change in inventories - materials and services
Sales margin%	(Sales margin / Revenue) x 100
EBITDA	Revenue + other operating income - change in inventories - materials and services -personnel expenses - other operating expenses
EBIT	Revenue + other operating income - change in inventories - materials and services -personnel expenses - other operating expenses - depreciation and amortization
Net profit (loss)	Revenue + other operating income - change in inventories - materials and services -personnel expenses - other operating expenses - depreciation and amortization – net financial expenses - income taxes
RD spend on total costs %	Research and development expenses / (personnel expenses + depreciation + other operating expenses) x 100
Equity ratio %	Total equity at the end of the period / (Total liabilities at the end of the period- advances received at the end of the period) x 100
Cash and cash equivalents	Cash and cash equivalents at the end of the period
Earnings per share (undiluted)	Profit (loss) of the period/shares outstanding at the end of the period
Earnings per share (diluted)	Profit (loss) of the period / (shares + convertible securities outstanding at the end of the period)

DECLARATION

DECLARATION OF THE BOARD OF DIRECTORS AND THE CEO

The Board and the CEO assure that this half year report gives a true and fair view of the development and the Group's operations, position, and results and describes significant risks and uncertainties faced by the Bioretec Group

Place: Tampere

Time: August 5, 2021

Timo Lehtonen
CEO

Tomi Numminen
Chairman of the Board

Michael Piccirillo
Member of the Board

Hans Rósen
Member of the Board

Pekka Simula
Member of the Board

Sarah Fisher
Member of the Board